510(k) Summary of Safety and Effectiveness

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

Submitter:

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Contact person: Randy Jiang

Date of Preparation: 2011-12-02

Proprietary Name: Patient Monitor Model elite V8

Classification:

Description	Classification	Product code
21 CFR 870.1025 monitor, physiological, patient(with arrhythmia detection or alarms)	II	MHX
21 CFR 870.2300 Cardiac monitor (including cardiotachoment and rate alarm)	II	DRT
21 CFR 870.1130 Non-Invasive blood pressure measurement System	II	DXN
21 CFR 870.1110 Blood pressure computer	II	DSK
21 CFR 880.2910 Clinical Electronic Thermometers-Temperature Monitor with Probe	II	FLL
21 CFR 870.2700 Oximeter, Pulse	II	DQA
21 CFR 870.1400 Carbon Dioxide Gas Analyzer	II	CCK
21 CFR 868.1500 Enflurane gas analyzer	II	CBQ
21 CFR 868.1620 Halothane gas analyzer	II	CBS
21 CFR 868.1700 Nitrous Oxide gas analyzer	II	CBR
21 CFR 868.1720 Oxygen gas analyzer	II	CCL
21 CFR 868.2900 cable, transducer and electrode, patient, (including connector)	II	DSA
21 CFR 870.2300 monitor, cardiac (incl. cardiotachometer & rate alarm)	II	DRT
21 CFR 870.1025 Detector and Alarm, Arrhythmia	II	DSI
21 CFR 870.1025 Monitor, ST Segment with Alarm	II	MLD

Regulatory Class: Class II

Legally Marketed Predicate Devices::

Manufacturer	Predicate Device	510(k) #	Cleared date
Edan Instruments, Inc	M3 and M3A	K102825	Dec.27.2010
Philips Medical System	MP70	K100939	April.1.2010
Edan Instruments, Inc	M3B	K083821	May.14,2009
ZOLL Medical Corporation	ZOLL M series NIBP option	K032363	July 30, 2003
PHASEIN AB	Carbon-dioxide gas analyzer	K103604	March.28,2011

Device Description:

The elite V8 Patient Monitor can perform long-time continuous monitoring of multiple physiological parameters. Also, it is capable of storing, displaying, analyzing and controlling measurements, and it will indicate alarms in case of abnormities happen.

The elite V8 realizes the monitoring of physiological parameters by configuration with different parameter modules which include SpO2 (pulse oxygen saturation, pulse rate and SpO2 plethysmogram) with EDAN SpO2 module or Nellcor SPO2 module, NIBP (systolic pressure, diastolic pressure, mean pressure and pulse rate), TEMP, ECG, RESP, CO2, IBP, C.O. and AG.

The above is the maximum configuration for elite V8, the user may select different monitoring parameters in according with the requirement.

Elite V8 configures with 17-inch touch screen and build-in Lithium-ion battery, Besides, elite V8 supports software upgrade online and networking.

Comparison with predicate device

The elite V8 Patient Monitors have the following similarities to that which previously received 510(k) concurrence:

- have the same indications for use,
- use the similar operating principle,
- have the same or similar performance specifications

In summary, the elite V8 Patient Monitor described in this submission is, in our opinion, substantially equivalent to the

predicate device

Intended Use:

This monitor is intended to be used for monitoring, storing, reviewing, recording, and generating alarms for multiple physiological parameters including ECG, respiration (RESP), temperature (TEMP), functional arterial oxygen saturation (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), expired CO2, cardiac output (C.O.) and anesthetic gas (AG)of adults, pediatrics and neonates in hospital environments.

This monitor is suitable for use in hospital environments including but not limited to OR, PACU, ICU and neonate intensive care room.

Contraindications: It is not intended for use in patient's home or residence, or when it has not been ordered by a physician.

Test Summary: The following quality assurance measures were applied to the development of the Patient Monitor

- Software testing
- Hardware testing
- Safety testing
- Environment test
- Risk analysis
- Final validation

Conclusion: Verification and validation testing was done on the Patient Monitor. This premarket notification submission demonstrates that Patient Monitor is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 16 2012

Edan Instruments, Inc.
c/o Mr. Randy Jiang
Regulation Affairs Engineer
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Nanhai Rd 1019#, shekou, Nanshan
Shenzhen 518067
P.R. China

Re: K120173
Trade/Device Name: Patient Monitor Elite V8
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: Class II (two)
Product Code: MHX, DRT, DXN, DSK, FLL, DQA, CCK, CBQ, CBS, CBR, CCL, DSA, DRT, DSI, MLD
Dated: April 24, 2012
Received: April 25, 2012

Dear Mr. Jiang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: Elite V8 Patient Monitor

This monitor is intended to be used for monitoring, storing, reviewing, recording, and generating alarms for multiple physiological parameters including ECG, respiration (RESP), temperature (TEMP), functional arterial oxygen saturation (SpO_2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), expired CO_2, cardiac output (C.O.) and anesthetic gas (AG)of adults, pediatrics and neonates in hospital environments. The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

This monitor is suitable for use in hospital environments including but not limited to OR, PACU, ICU and neonate intensive care room.

Prescription Use ____×____ And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120173